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EXAMINER	
PANI, JOHN	

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3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,926	KAMO ET AL.	
	Examiner	Art Unit	
	John Pani	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/04/07.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. The specification contains multiple instances of wording that appears to be a direct translation to English from a foreign language which make it impossible to accurately assess the nature of the parts and operation of the invention. Applicant's cooperation is requested in thoroughly revising the specification and correcting any errors of which applicant may become aware in the specification.

The following is a list of exemplary errors. Note that the list is not to be considered to be inclusive of all the errors present, but is merely provided to point out the types of errors that need correction:

a. On the final line of page 12 through the third line of page 13, it is unclear what is meant by the entire paragraph. The paragraph refers to results obtained by "superposing a spinal rooting sense diagram...", but does not appear to previously describe what kind of results/data these are.

b. On pg. 15 line 12 – pg. 16 line 12, it is unclear what the data extraction unit is doing. For example, it is unclear where the data extracting unit is extracting data from and how it is doing this, in addition to what exactly is meant by "extracting". For example, this could be construed to mean decompressing compressed data, etc.

c. On pg. 17 lines 6-23, it is unclear what the responsible lesion estimation/indication unit is doing because the nature of the "responsible nerve pathways" is never clearly described.

d. On pg. 17 line 24 – pg. 18 line 8, it is unclear what the third responsible lesion estimation/indication unit is or does, as language such as "excludes a responsible nerve pathway part corresponding to nerve fascicles for connecting a muscle a finding data (electromyogram data) of which is to be a normal finding with the relevant spinal roots" is not in proper idiomatic English.

The applicant's assistance in correcting all similar instances throughout the specification is requested and required in order to allow for the true scope of the invention to be determined. The revision must not contain new matter. The revision must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version

(without markings) and a statement that the revised specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Claim Objections

3. Claims 1-15 objected to because of the following informalities: In claims 1-15 is it suggested to replace "characterized by that" with –wherein— or –comprising—as appropriate. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

7. The following is a list of exemplary errors leading to indefiniteness. Note that the list is not to be considered to be inclusive of all the errors present, but is merely provided to point out the types of errors that need correction. Similar errors are present in each of the claims:

In reference to Claim 1

In lines 5-6, it is unclear what is meant by the act of "receiving normal finding or abnormal finding data input with respect to respective neural finding items". For example, this could be construed to mean that the data input unit is receiving data that is either "normal" or "abnormal" with respect to each "neural finding item", or that it is receiving "normal" and "abnormal" data with respect to each "neural finding item". Further, it is unclear what is meant by "neural finding items".

In lines 7-11, it is unclear how the unit draws a responsible nerve pathway "relating to neural finding items being in an abnormal finding from the data stored...". It is unclear whether the responsible nerve pathway is drawn based on data in the whole nerve pathway diagram data recording unit, or is drawn based on data received in the nerve finding data input unit, or using data from both. It is further unclear what exactly the responsible nerve pathway is "responsible" for based on the claims as currently written.

In line 20, the use of the term "estimation/indication unit" is indefinite, as it is unclear whether this language requires that the unit estimate AND indicate, or merely that the unite estimate OR indicate. In addition, it is unclear whether the unit is actually calculating the position of a lesion, or is merely "taking the position for granted in the absence of proof to the contrary", as is the generally accepted meaning of "presume".

In addition, it is unclear whether the claimed "units" are physical, circuitry based units, or are instead computer based functions, or whether the claims are intended to encompass both options.

In reference to Claim 2

It is unclear whether the claim as written requires all of the types of data described after "at least" in line 2. In lines 5-6 it is unclear what is meant by "curves or straight lines representing nerve fascicles for connecting the nerve nuclei with each other", as this language could be construed to mean that that data is predetermined, or that the data is created for each use.

In reference to Claim 3

In lines 6-7 it is unclear what is meant by extracting data "in every neural finding items exhibiting abnormal findings.

In reference to Claim 4

In line 5 it is unclear whether "the region" is referring to "a region" in line 2, or a "a region" in line 4.

In reference to Claim 5

In lines 3-4 it is unclear whether the "nerve pathway cut surface data recording unit" is storing "cut surface data" within "specified region in said whole nerve pathway diagram", as it is unclear how data would be stored within a diagram, or whether another meaning was intended, such as that the whole nerve pathway diagram was somehow integrated with the cut surface.

In lines 5-7, it is unclear whether the cut surface is displayed "in the whole nerve pathway diagram", or whether a section of the whole nerve pathway diagram is being shown as a cut surface, etc.

In lines 8-13, it is unclear how the unit draws a responsible nerve pathway "relating to neural finding items being in an abnormal finding onto a cut surface of relevant specified region from the data stored...." It is unclear whether the responsible nerve pathway is drawn based on data in the nerve pathway cut surface data recording unit, or is drawn based on data received in the nerve finding data input unit or using data from both. It is further unclear what the "relevant specified region" is a region of, for example, a region of the body, a region of a previous cut surface, a region of a new cut surface, etc. In addition, the use of the term "relevant" renders the claim indefinite, as "relevant" is a subjective term.

In lines 14-17 it is unclear whether the cut surface data is being extracted from data stored in the nerve pathway cut surface data recording unit or input by the cut surface display region selection data input unit.

In lines 18-21 it is unclear whether the responsible nerve pathway is being displayed in a previously described nerve pathway cut surface or an additional cut surface, and it is further unclear how responsible nerve pathways are drawn in the cut surfaces, as the term "responsible nerve pathway" is used to refer to what is drawn in "whole nerve pathway diagrams" in claim 1.

In lines 22-25 the use of the term "estimation/indication unit" makes it unclear whether the unit is estimating OR indicating, or estimating AND indicating. In addition, it is unclear whether the unit is actually calculating the position of a lesion, or is merely "taking the position for granted in the absence of proof to the contrary", as is the generally accepted meaning of "presume". Finally, it is further unclear whether the

location of the lesion is based on the actual cut surface diagram, or based on other data and then displayed on the diagram.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/17614 to Fardin ("Fardin").

10. Please note: The use of "for" statements such as "for storing data of whole nerve pathway diagrams" are merely statements of intended use which do not structurally limit the claimed apparatus except by requiring that the device be capable of this function. It is suggested to amend the claims such that they positively describe structures that perform the intended uses. Due to the prior mentioned issues related to indefiniteness, application of prior art has been made according to the examiner's best understanding of the invention.

11. Fardin teaches:

In reference to Claim 1

A nerve diagnostic system with the use of a computer (pg. 22 lines 11-25), wherein the nerve diagnostic system comprises: a whole nerve pathway diagram data recording unit (first anatomic diagram **4** and second anatomic diagram **6** are displayed

on a display when the unit is turned on, pg. 9 lines 1-5, and the data is stored or "held", pg. 15 lines 20-25, thus a memory of some type is inherent) for storing data of whole nerve pathway diagrams; a nerve finding data input unit (keys **8**, in combination with processor, memory, and function that accepts input of motion deficit evaluation) for receiving normal finding or abnormal finding data input with respect to respective neural finding items (see pg. 16 line 19 – pg. 17 line 19); a responsible nerve pathway data extraction unit (a function within the processor with which "the nervous trunks that may be the sites of the lesions are displayed", pg. 19 lines 4-10 would inherently extract data) for extracting data for drawing a responsible nerve pathway relating to neural finding items being in an abnormal finding from the data stored in said whole nerve pathway diagram data recording unit based on the data received in said nerve finding data input unit; a display unit (display **9**); a whole nerve pathway indication unit (a function within the computer that displays first anatomic diagram **4** and second anatomic diagram **6** on display **9** is inherently present, see for example pg. 16 lines 14-19) for displaying a whole nerve pathway diagram on said display unit based on the data stored in said whole nerve pathway diagram data recording unit; a responsible nerve pathway indication unit (In step 17 the processor determines the nervous trunks that may be the sites of the lesion and then displays them, see pg. 18 lines 4-10) for displaying a responsible nerve pathway in the whole nerve pathway diagram displayed on said display unit by said whole nerve pathway indication unit based on the data extracted by said responsible nerve pathway data extraction unit (the nervous trunks are highlighted on the first and second diagrams); and a responsible lesion

estimation/indication unit (the processor inherently determines the location of the lesion prior to being capable of displaying which nervous trunks may be the site of lesion, pg. 18 lines 4-10) for presuming a position of a responsible lesion in said whole nerve pathway diagram based on the responsible nerve pathway displayed on said display unit by said responsible nerve pathway indication unit.

In reference to Claim 2

The nerve diagnostic system of claim 1 (see above) wherein the data (see Fig. 1B, a depiction of the anatomic diagrams, which is inherently stored) stored in said whole nerve pathway diagram data recording unit contains data of at least names and positions of respective nerve nuclei in the whole nerve pathway diagram ("ULNAR N.", diagram shows positions of nerves relative to muscles and other nerves), connection relations in the respective nerve nuclei (branching areas show connections), and curves or straight lines representing nerve fascicles for connecting the nerve nuclei with each other (straight lines represent nerves).

In reference to Claim 3

The nerve diagnostic system of claim 2 (see above) wherein the responsible nerve pathway data extraction unit is adapted to extract data of relevant names and positions of nerve nuclei in the whole nerve pathway diagram, relevant connection relations in the respective nerve nuclei, and curves or straight lines representing nerve fascicles for connecting the relevant nerve nuclei with each other from said whole nerve pathway diagram data recording unit in every neural finding items exhibiting abnormal findings (The processor is inherently adapted to extract the above information, as it

takes it from memory and displays it, see rejection of claim 2. In addition, this can occur each time a new motion deficiency evaluation occurs).

In reference to Claim 4

The nerve diagnostic system of claim 3 (see above) wherein the responsible lesion estimation/indication unit is adapted to detect a region where responsible nerve pathways displayed on said display unit intersect with each other and a region where said responsible nerve pathways approach one another in the closest relation, and presume the region detected to be a responsible lesion thereby to display the responsible lesion in said whole nerve pathway diagram on said display unit (In order to display what is shown in Fig. 1B, the processor must be adapted to detect a region where the nerve pathways intersect each other and approach one another in closest relation, as the display shows instances when these instances occur, and draws them. Because the processor determines the likely location of the lesion, whenever this occurs where nerve pathways on the diagram are close together, the claimed condition would be met).

In reference to Claim 11

The nerve diagnostic system of claim 1 (see above) wherein the data (see Fig. 1B, a depiction of the anatomic diagrams, which is inherently stored, and pg. 21-22) stored in said whole nerve pathway diagram data recording unit contains data of at least names and positions of respective spinal roots (see Fig. 1B), respective muscles and respective skin areas in the whole nerve pathway diagram see Figs. 6A-7), connection relations in the respective spinal roots and the respective muscles (branching areas

show connections between spinal roots, Fig. 6B shows connection relations between spinal roots and muscles), and curves or straight lines representing nerve fascicles for connecting the respective spinal roots with the respective skin as well as data of connection relations in the respective spinal roots and the respective skin areas and curves or straight lines for connecting the respective spinal roots with the respective skin areas (See Fig. 6C).

In reference to Claim 12

The nerve diagnostic system of claim 11 (see above) wherein the responsible nerve pathway data extraction unit is adapted to extract data of relevant names and positions of spinal roots, muscles and skin areas in the whole nerve pathway diagram, relevant connection relations in the respective spinal roots and the respective muscles, and curves or straight lines representing nerve fascicles for connecting the relevant respective spinal roots with the respective skins as well as data of relevant connection relations in the respective spinal roots and the respective skin areas, and curves or straight lines for connecting the relevant respective spinal roots with the respective skin areas from said whole nerve pathway diagram data recording unit in every neural finding items exhibiting abnormal findings (The processor is inherently adapted to extract the above information, as it takes it from memory and displays it, see rejection of claim 2. In addition, this can occur each time a new motion deficiency evaluation occurs.).

In reference to Claim 13

The nerve diagnostic system of claim 12 (see above) wherein the responsible lesion estimation/indication unit is adapted to detect a region where responsible nerve pathways displayed on said display unit intersect with each other and a region where said responsible nerve pathways approach one another in the closest relation, and presume the region detected to be a responsible lesion thereby to display the responsible lesion in said whole nerve pathway diagram on said display unit (In order to display what is shown in Fig. 1B, the processor must be adapted to detect a region where the nerve pathways intersect each other and approach one another in closest relation, as the display shows instances when these instances occur, and draws them. Because the processor determines the likely location of the lesion, whenever this occurs where nerve pathways on the diagram are close together, the claimed condition would be met).

In reference to Claim 14

The nerve diagnostic system according to claim 13 (see above) further comprising a third responsible lesion estimation/indication unit (the processor excludes nerve pathways which are running through muscles that are not altered, see Table 1) excluding a responsible nerve pathway part corresponding to nerve fascicles (the various nerves are nerve fascicles) for connecting a muscle or skin region (the muscles connect muscles) in which finding data input comes to be a normal finding (i.e. no muscular deficit) with the spinal roots relating thereto from the responsible nerve pathways displayed in said whole nerve pathway diagram on the display unit by means of said responsible lesion estimation/indication unit in the case when the finding data

input as to abnormality of respective muscles or respective skin regions relating to said responsible nerve pathways is received by said nerve finding data input unit (processor always receives input related to abnormality of respective muscles).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fardin.

In reference to Claims 10 and 15

Fardin teaches the system of claims 1-4 (see above) and 14, but does not teach that the basis for motion deficit evaluation includes each of the symptoms described in claim 10. However, Fardin teaches that when localizing a lesion, the clinician includes as much information as possible from the patient's clinico-electromyographical examinations (see pg. 4 lines 14-19). Thus it was recognized that a variety of information sources could be used to diagnose neural lesions. In addition, a finite number of potential solutions would provide predictable results. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the system of Fardin by including additional symptoms that are indicative of

various neural lesion locations in the algorithm for determining the location of neural lesions. The modification would have a reasonable expectation of success.

Allowable Subject Matter

14. The subject matter of claims 5-9 appears to be allowable over the prior art of record if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Due to the issues regarding indefiniteness, the examiner reserves the right to later reject the claims based on either the prior art of record or new art pending revision of the claims, as currently the scope of the claims are unclear.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat. No. 6,925,199 to Murao discloses a computer readable recording medium and a method for detecting lesion positions which includes lesion position detection, lesion feature extracting, and disease name and probability calculating. The method uses segmented images. US 6,249,594 to Hibbard teaches of a method for imaging lesions which uses cut surfaces.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Pani whose telephone number is 571-270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 10/23/07

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